<u>REMARKS</u>

THE OFFICE ACTION

Claims 41-87, pending, are rejected. Also, by the Office Action,

- (i) A list of co-pending patents and applications that may present double patenting issues with the instant Application is requested.
 - (ii) Fig. 23 of drawing sheet 21 is missing; drawing sheet 21 is requested.
- (iii) An update to cross-referenced applications and patents cited in the specification is requested.
- (iv) Claims 41-48, 55, 59-61, 56, 67-73, 81, and 85-86 are rejected under 35 U.S.C. 103 (a) as being unpatentable over U.S. Patent no. 5,389,096 (Aita '096) in view of U.S. Patent no. 5,902,289 (Swartz '289).

In this rejection, the Office Action cites Aita '096 for disclosing a laser catheter device for performing percutaneous myocardial revascularization (PMR), by advancing a catheter into the ventricle of the heart and forming channels in the heart wall. However, the Office Action notes that Aita '096 fails to disclose the use of electrosurgical energy (RF) as the treatment energy.

Swartz '289, however, according to the Office Action, teaches another cardiac treatment catheter, and also teaches that it is generally known to substitute various energy modalities including RF or laser energy in a cardiac ablation catheter for ablating cardiac tissue (Col. 11, lines 3-12).

Thus, according to the Office Action, it would have been obvious to substitute an RF energy catheter, based on Swartz '289, for the laser energy of catheter of Aita '096 to perform a PMR procedure.

(v) Claims 49, 50, 74-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aita '096 and Swartz '289 as per above, and further in view of U.S. Patent no. 5, 380,316 (Aita '316).

In this rejection, the Office Action, cites Aita '316 and Swartz '289 as per above, and also Aita '316 for disclosing percutaneously accessing a ventricle of the heart to perform the procedure, but failing to disclose performing revascularization from the epicardium side of the heart.

However, according to the Office Action, Aita '316 discloses essentially the same procedure of Aita '096, but teaches that it is known to perform revascularization from the epicardial side of the heart.

Thus according to the Office Action, it would have been obvious to perform the Aita '316 procedure from the epicardial side of the heart, particularly since Aita '096 teaches that it is known to the procedure epicardially.

(vi) Claims 51-54, 56-58, 66, 76-80, 82-84 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aita '096 and Swartz '289 as per above, further in view of US Patent no. 4,682,596 (Bales).

In this rejection, the Office Action cites Aita '096 and Swartz '289 as per above, and further notes that while Swartz teaches that it is known to substitute RF energy for laser energy in cardiac procedures, Swartz fails to teach the electrode arrangement (bipolar, monopolar, etc) provided on the Applicant's catheter. Also, Swartz does not teach the use of conductive fluid at the treatment site, or of providing suction to the treatment site.

However, according to the Office Action, Bales discloses another RF catheter for treating cardiac tissue, and in particular Bales teaches that it is known to provide a variety of electrode arrangement including monopolar and bipolar configurations. Further, Bales teaches providing a saline solution at the tissue site, and a suction to remove fluid and debris from the treatment site.

Thus according to the Office Action, it would have been obvious to provide the Aita system, as modify Swartz '289, with the well-known electrode arrangement of Bales. Further, it would have been obvious to provide Aita's system with a saline line and a suction means in view of Bales.

(vii) Claim 62 is rejected under 35 USC 103 (a) as being unpatentable over Aita '096 and Swartz '289 further in view of U.S. Patent no. 5,891,133 (Murphy-Chutorian).

In this rejection, the Office Action cites Aita '096 and Swartz '289, and further indicates that although Aita '096 discloses percutaneously accessing ventricle of the heart to create channels in the hear tissue, Aita '096 fails to disclose inserting a prosthesis (i.e. a stent) in the channel to maintain patency of the channel.

However, according to the Office Action, Murphy-Chutorian disclose the same procedure (TRM), and specifically teach that it is advantageous to insert a radially expandable stent into the revascularized tissue.

Thus according to the Office Action, it would have been obvious to provide the Aita system width the prosthesis (stent) to maintain patency, in view of Murphy-Chutorian.

(viii) Claims 63-64 are rejected under 35 U.S.C. 103(a) in view of Aita '096 and Swartz '289 further in view of U.S. Patent no. 5,766,164 (Mueller).

In this rejection, the Office Action notes that in addition to combined teachings of Aita and Swartz as per above, Aita '096 discloses percutaneously accessing a ventricle in the heart to create channels in the heart tissue, but fails to teach U-shaped channels.

Mueller, according to the Office Action, discloses another system for creating channels in heart tissue, and in particular teaches that it is advantageous to create curved and/or U-shaped channels.

Thus according to the Office Action, it would have been obvious to use the Aita system in view of Mueller to create curved and or U-shaped channels to improve blood perfusion in cardiac tissue

(ix) Claims 1-3, 6-8, 10-11, 15-17 and 23-27 are rejected under the judicially created doctrine of obviousness-type double patenting over various cited claims of U.S. Patents no. 5, 873, 855; 5,683,366; 5,697,281; 5,697,882; 6,032, 674; and U.S. Patent Application no. 09/3347,390.

<u>RESPONSE TO THE OFFICE ACTION</u>

1. The request for list of document re. double patenting issues

An updated Information Disclosure Statement (IDS) is herewith provided.

2. The missing Fig. 23

Replacement sheet 21/21 containing originally filed Fig. 23 is enclosed. Nothing is changed on this sheet. Accordingly, withdrawal of this objection is respectfully requested

- 3. <u>Updated Cross-referenced patent Applications and Patents in the Specification</u>
 An update to cross-referenced applications in paragraph at page 1, lines 9-24 of
 Specification is enclosed. Accordingly, withdrawal of this objection is respectfully requested.
 - 4. Rejection of Claims 41-48, 55, 59-61, 65, 67-73, 81, 85-86 under 35 U.S.C. 103 (a) as being unpatentable over Aita '096 in view of Swartz '289

Claim 41 is amended to specify that the method of <u>volumetric removing of tissue</u> from a portion of a patient's myocardium comprising: positioning an <u>active</u> electrode terminal in close proximity to a target site on a wall of the patient's heart <u>in the presence of an electrically conductive fluid</u>; inducing a discharge of energetic electrons and photons at said active electrode <u>by</u> applying a <u>sufficient</u> high frequency voltage to the <u>active</u> electrode terminal <u>and a return</u> electrode and directing the energetic electrons and protons to volumetrically remove tissue at the target site.

By this amendment it is believed that the claims are patentable over all the cited references because none of these references teach or suggest inducing a discharge of energetic electrons and photons at said active electrode by applying a sufficient high frequency voltage to the active electrode terminal and a return electrode and directing the energetic electrons and protons to volumetrically remove tissue. Accordingly, withdrawal of this objection is respectfully requested.

5. Rejection of Claims 49-50, 74-75 under 35 U.S.C. 103 (a) as being unpatentable over Aita '096 and Swartz '289, in view of Aita '316

For the reasons set forth above it is believed that the claims are patentable over all the cited references because none of these references teach or suggest inducing a discharge of energetic electrons and photons at said active electrode by applying a sufficient high frequency voltage to the active electrode terminal and a return electrode and directing the energetic electrons and protons to volumetrically remove tissue. Accordingly, withdrawal of this objection is respectfully requested.

6. Rejection of Claims 51-54, 56-58, 66, 76-80, 82-84 and 87 under 35 U.S.C. 103(a) as being unpatentable over Aita '096 and Swartz '289 as per above, further in view of Bales

For the reasons set forth above it is believed that the claims are patentable over all the cited references because none of these references teach or suggest inducing a discharge of energetic electrons and photons at said active electrode by applying a sufficient high frequency voltage to the active electrode terminal and a return electrode and directing the energetic electrons and protons to volumetrically remove tissue. Accordingly, withdrawal of this objection is respectfully requested.

7. <u>Rejection of Claim 62 under 35 U.S.C. 103(a) as being unpatentable over Aita</u> '096 and Swartz '289 as per above, further in view of Murphy-Chutorian

For the reasons set forth above it is believed that the claims are patentable over all the cited references because none of these references teach or suggest inducing a discharge of energetic electrons and photons at said active electrode by applying a sufficient high frequency voltage to the active electrode terminal and a return electrode and directing the energetic electrons and protons to volumetrically remove tissue. Accordingly, withdrawal of this objection is respectfully requested.

8. Rejection of Claim 63-64 under 35 U.S.C. 103(a) as being unpatentable over Aita '096 and Swartz '289 as per above, further in view of Mueller

For the reasons set forth above it is believed that the claims are patentable over all the cited references because none of these references teach or suggest inducing a discharge of energetic electrons and photons at said active electrode by applying a sufficient high frequency